

1. Only the practitioner with the DEA registration may authorize a controlled substance medication. Determining whether a controlled substance is needed must be determined by the prescriber and cannot be delegated.
2. The responsibility for issuing a proper and legal prescription is upon the prescribing practitioner, with a corresponding liability and responsibility by the pharmacy. When prescriptions arrive at a pharmacy, they must meet all of the requirements before being dispensed. This responsibility is on the pharmacy.
3. All controlled substance prescriptions must be issued completely with all of the information required documented on the prescription. All controlled substance prescriptions issued on paper, or faxed, must be physically and manually signed by the prescribing practitioner;
  - Prescriptions presented to pharmacies by the patient must be signed in original ink;
  - Prescriptions faxed to pharmacies must be physically signed by the prescriber before they are faxed. Electronic and digital signatures cannot be used;
  - Prescriptions may be communicated by telephone to a pharmacy by the doctor's agent;
  - Prescriptions may be transmitted electronically to a pharmacy only in accordance with DEA regulations 21 CFR 1306.05(e) and 21 CFR 1311.140.
4. The Roles of Agents:

Congress recognized the roles of "agents" as an authorized person who acts on behalf of or at the direction of a dispenser. Likewise, DEA regulations permit a practitioner to use an authorized agent to perform certain ministerial acts in connection with communicating prescription information to pharmacies. These acts would include hand delivery, facsimile (*after the prescriber's signature*), telephone calls, or sending an electronic transmission after the prescriber has provided the signature. As explained in a more detailed chart below, the proper role of an agent depends upon the schedule of the controlled substance prescribed, the circumstances of the ultimate user and the method of communication.

Schedule II Controlled Substances	Schedule III—V Controlled Substances
<p>Prescriber may write in original ink</p> <p>Prescriber may electronically transmit per DEA regulations with e-signature</p> <p>No refills are authorized</p> <p>May be telephoned and communicated orally in an emergency by the prescriber only. An agent may never phone in an emergency CII medication. Prescriber must provide pharmacy with a written prescription within 7 days or pharmacy is required to report the prescriber to the BNDD and DEA.</p> <p><u>Faxing Schedule II prescriptions:</u></p> <ol style="list-style-type: none"> <li>1. For patients in LTCFs;</li> <li>2. For patients in hospice care;</li> <li>3. Prescriptions must be documented that patient is in a LTCF or hospice care;</li> <li>4. May only be faxed, after the prescriber has manually signed the prescription</li> </ol> <p>A CII prescription is only valid for six months after the date it is written.</p> <p>Most are for 30-day supply or less.</p> <p>Greater than 30-days requires a medical reason on the prescription.</p> <p>A prescriber can issue multiple prescriptions with “do not fill until _____” dates on them as long as they do not exceed a 90-day supply.</p> <p>Patients in LTCFs and hospice care may have prescriptions partially filled in increments as long as the pharmacy does not exceed the total quantity prescribed.</p>	<p>Prescriber may write in original ink</p> <p>Prescriber may electronically transmit per DEA regulations with e-signature</p> <p>5 refills are authorized within 6 months of date the prescription was signed</p> <p>May be telephoned by the prescriber or their agent. All elements must be reduced to writing by the pharmacy.</p> <p>May be faxed to a pharmacy only after the prescriber has signed the prescription.</p> <p>These prescriptions are valid for 6 months after the date they are signed.</p> <p>The quantity is limited to a 90-day supply on one prescription.</p> <p><u>For Schedule 5 Drugs Only:</u></p> <ol style="list-style-type: none"> <li>1. A prescription is a valid for one year from the date signed;</li> <li>2. A prescriber may allow refills as needed “PRN” for up to one year as the prescriber allows.</li> </ol>

5. Who is considered an agent of the prescriber?

The Controlled Substances Act (CSA) defines an "agent" as "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. Establishment of an agency relationship, consistent with the CSA, is guided by general precepts of the common law of agency. For the purposes of explaining the law of agency as it relates to the CSA, it is appropriate to refer to and consider as generally applicable the Restatement of Agency (Restatement) which provides:

Agency is the fiduciary relationship that arises when one person (a "principal") manifests assent to another person (an "agent") that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act. Restatement (Third) of Agency Sec. 1.01 (2006).

The Restatement is useful in evaluating whether, for CSA purposes, a valid agency relationship exists between a prescribing practitioner and another person for the purpose of communicating a prescription for a controlled substance to a pharmacy. The Restatement requires that the principal (in this context, the DEA-registered individual practitioner) "manifests assent" for a certain person to act on his or her behalf. This is consistent with the CSA and its registration-based system of accountability. Where non-DEA registrants communicate a prescription for a controlled substance on behalf of a registrant, it is important that such persons be clearly identified and their activities be subject to evaluation to ensure they do not exceed the bounds of the agency relationship and the legal limits of an agent's role under the CSA. Because the individual practitioner remains responsible for ensuring that all prescriptions issued pursuant to his or her DEA registration comply in all respects with the CSA and DEA regulations, it is important that the practitioner decide who may act as his or her agent. This is also consistent with the CSA definition that an agent is "an authorized person who acts on behalf of or at the direction of" the prescribing individual practitioner.

In addition to requiring that the principal (i.e., individual prescribing practitioner) "manifests assent" to having a particular person act as his or her agent, and that the agent reciprocate by manifesting assent to serve as such, the Restatement also requires that the agent acts "subject to the principal's control." In an employment situation, an individual practitioner may establish the duties of his or her employees and is responsible for monitoring their activities. Absent an employer-employee relationship, a practitioner will generally have less control over other persons that he or she may designate as his or her agent(s). Prior to designating an agent, a practitioner may wish to consider the degree of control that the registrant may exercise over the proposed agent, the proposed agent's licensure, level of training and experience, and other such factors to determine whether the person would be an appropriate agent and to ensure that the agent will not engage in activities that exceed the scope of the agency relationship. Absent affirmative actions by the practitioner and the proposed agent, a valid agency relationship generally will not exist outside an employer-employee relationship.

By requiring that an agency relationship is created when (1) the principal manifests assent that a particular person shall act (i) on his or her behalf and (ii) subject to his or her control, and (2) the agent manifests assent so to act, the Restatement definition of "agency" is consistent with the CSA's definition of "agent" as "an authorized person who acts on behalf of or at the direction of" the prescribing practitioner. An agent may not legally perform duties that must be personally performed by the individual practitioner. The practitioner may assign only those duties which may be carried out by an agent.

DEA notes that in a 2001 notice and solicitation of information on the potential use of automated dispensing systems to prevent the accumulation of surplus controlled substances at LTCFs, DEA briefly discussed the role of nurses in the narrow setting of LTCFs outside of an employer-employee relationship and where no affirmative actions established an agency relationship between the individual practitioner and the LTCF nurse. 66 FR 20833, 20834 (April 25, 2001). This incidental example and other informal discussions have resulted in the need for this published articulation of what existing law allows and what affirmative actions may be required to establish a valid agency relationship for purposes of an authorized agent to communicate controlled substance prescriptions to pharmacies, particularly in settings where there is no employer-employee relationship. DEA regulations on

the role of authorized agents in communicating controlled substance prescriptions to pharmacies generally have not changed.

This policy statement outlines the proper role of agents in those situations where an individual practitioner and an individual agent (including but not limited to an LTCF nurse) have taken affirmative steps to establish a valid agency relationship for those aspects of the CSA that may be appropriately executed by an authorized agent under Federal law. As such, DEA is hereby outlining a suggested mechanism to establish a valid agency relationship as well as explaining the appropriate roles an authorized agent may play regardless of the setting. This statement of policy is intended to provide general guidance on establishment of a valid agency relationship between an individual practitioner and an identified individual. DEA wishes to emphasize that, regardless of the setting, it is the practitioner's sole decision as to whether or not to designate an agent to act on his or her behalf and subject to his or her control. To be consistent with the purpose of the CSA to implement a "closed system" of distribution and for DEA to enforce this framework, an agency relationship between a registered individual practitioner and an identified agent for the purposes of communicating controlled substance prescriptions must be explicit and transparent. DEA believes its existing regulations are adequate in addressing the role of an authorized agent but will analyze whether additional federal rulemaking or guidance is needed beyond this statement to establish the necessary explicit and transparent nature of an authorized agency relationship, particularly when outside an employer-employee relationship.

#### 6. Written Agreements Between Prescribers and Agents—Sample Agreements

Due to the legal responsibilities of practitioners and pharmacists under the CSA and the potential harm to the public from inappropriate and unlawful prescribing and dispensing of controlled substances, violations of the law are subject to criminal, civil, and administrative sanctions. DEA believes it is in the best interests of the practitioner, the agent, and the dispensing pharmacist that the designation of those persons authorized to act on behalf of the practitioner and the scope of any such authorization be reduced to writing.

DEA provides below an example of a written agreement that would properly confer authority to an agent to act on behalf of an individual practitioner with regard to controlled substance prescriptions. Individual practitioners may choose to designate and authorize one or more persons at one or more locations within or outside their practice to act as their agent. Likewise, an individual may act as an authorized agent for multiple individual practitioners depending upon the circumstances. A practitioner may or may not wish to delegate all of these types of authorized communications to a particular agent and may tailor the agreement accordingly. The agreement should be clear that the agent may not further delegate the outlined responsibilities.